

**Analysis of the Benefit in Developing More Stringent
Human Health Water Quality Criteria**

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I. Introduction and Summary.

The Washington Department of Ecology (Ecology) is developing state human health water quality criteria (HHWQC).¹ An important factor in deriving HHWQC for carcinogens is the acceptable risk level used to calculate the criteria. The existing Ecology risk policy protects the average consumption rate for the general population to a one-in-one million (10^{-6}) increased risk of cancer as long as subpopulations are protected to a level that is no less than a one-in-ten-thousand (10^{-4}) increased risk of cancer.

The HHWQC applicable to Washington under the NTR are based on a fish consumption rate of 6.5 grams per day (g/day) for the general population, while higher consuming subpopulations are protected up to a fish consumption rate of 650 g/day. Based on this policy the existing human health criteria for carcinogens² in Washington are protective of consumption rates in all subpopulations documented in Ecology's Fish Consumption Rate Technical Support Document (TSD), No. 12-09-058 (Jan. 2013). The TSD identified tribal fish consumption rates at the 90th percentile of between 130 and 397 g/day. *Id.* at 5. The existing criteria are accordingly protective, at least as to carcinogens, within the state and federal risk policies for deriving human health criteria.

EPA guidance continues to this day to support deriving HHWQC based on protection of the general population to a risk level of 10^{-6} as long as subpopulations are protected to at least 10^{-4} .³ EPA guidance further recommends that states revise their human health criteria, or in the case of Washington, develop their own human health criteria, where there is evidence that subpopulations are not protected to 10^{-4} .⁴

¹ For information on the status of Ecology rule development see <http://www.ecy.wa.gov/toxics/fish.html>.

² The NTR includes chemicals that are listed as carcinogens for which there is no acceptable exposure level as well as chemicals that have threshold or dose response toxic effects. This discussion is limited to the risk policy as applied to carcinogens.

³ "EPA believes that both 10^{-6} and 10^{-5} may be acceptable for the general population and that highly exposed populations should not exceed a 10^{-4} risk level." EPA, *Methodology for Deriving Ambient Water Quality Criteria for the Protection of Human Health*, EPA-822-B-00-004, at 2-6 (Oct. 2000). EPA, *Technical Support Document for Action on the State of Oregon's New and Revised Human Health Water Quality Criteria for Toxics and Associated Implementation Provisions Submitted July 12 and 21, 2011*, at 27 (Oct. 17, 2011).

⁴ *Id.*

The adoption of HHWQC by Ecology constitutes a significant legislative rule within the meaning of the Administrative Procedures Act (APA). Before adopting human health criteria Ecology must conduct a cost benefit analysis, articulate a benefit to public health and welfare, and make a determination based on substantial evidence that the adoption of criteria differing from that set out in the NTR is necessary to achieve the goals and objectives of the Clean Water Act (CWA).

II. Administrative Procedures Act Rulemaking Requirements.

Several key requirements in the APA apply to Ecology's proposed adoption of state HHWQC. Ecology has acknowledged that adoption of the criteria will constitute a significant legislative rule subject to RCW 34.05.328. Before adopting a significant legislature rule Ecology must clearly state in detail the general goals and specific objectives of the statute that the rule implements. RCW 34.05.328(1)(a). It must make a determination that the rule is needed to achieve those goals and objectives, and must analyze alternatives to rulemaking and the consequences of not adopting the rule. RCW 34.05.328(1)(b).

Ecology must conduct a cost-benefit analysis, and must determine that the probable benefits of the rule are greater than its probable costs, taking into account both qualitative and quantitative benefits and costs, and the specific directives of the statute being implemented. RCW 34.05.328(1)(d). A preliminary cost-benefit analysis must be prepared at the time a draft rule is published for public comment, with a final cost-benefit analysis issued when the rule is adopted. RCW 34.05.328(1)(c).

Ecology must also conduct a "least burdensome alternative" analysis, determining, after considering alternative versions of the rule, that the rule being adopted is the least burdensome alternative for those required to comply with it that will achieve the general goals and specific objectives identified under RCW 34.05.328(1)(a). RCW 34.05.328(1)(e).

Ecology must additionally determine whether the rule is more stringent than federal standards. If so, Ecology must make a determination that the difference is justified either by a state statute that explicitly allows the agency to differ from federal standards or by "substantial evidence" that the difference is necessary to achieve the general goals and specific objectives stated under RCW 34.05.328(1)(a); RCW 34.05.328(1)(h).

Prior to adoption Ecology must also provide an implementation plan that describes how the agency intends to implement and enforce the rule, including a description of the resources the agency intends to use, how the agency will inform and educate affected persons about the rule, how the agency will promote and assist voluntary compliance, and an evaluation of whether the rule achieves the purpose for which it was adopted. RCW 34.05.328(3).

Finally, with regard to rulemaking related to Ecology's water quality program, the agency must identify the sources of information reviewed and relied upon in preparing a significant legislative rule.⁵

Should Ecology fail to comply with these APA requirements, its adoption of HHWQC may be deemed arbitrary and capricious by a reviewing court. Legislative findings appended to RCW 34.05.328 include a clear directive that courts reviewing administrative rules should "determine whether the agency decision making was rigorous and deliberative; whether the agency reached its result through a process of reason; and whether the agency took a hard look at the rule before its adoption."⁶ Ecology cannot merely assume that adopting more stringent human health water quality criteria will benefit public health and welfare. Rather, it must do a thorough analysis of the costs and benefits of doing so, and must articulate a justification for differing from the criteria already set forth in the NTR. Any such analysis must include an understanding of the risk policies attendant to human health water quality criteria that have been consistently applied and approved by the EPA for over twenty years.

III. State Water Quality Standards and Criteria for Toxic Contaminants.

Under the CWA, states are responsible for establishing water quality standards "to protect the public health or welfare, enhance the quality of water, and serve the purposes of the [Clean Water Act]." 33 U.S.C. § 1313(c)(2)(A) (Section 303). Water quality standards are used to derive the water quality based effluent limits contained in NPDES permits.⁷

Water quality standards consist of designated uses of a waterbody and water quality "criteria," 33 U.S.C. § 1313(c)(2)(A) (also referred to "ambient water quality criteria"), along with an antidegradation statement, 40 C.F.R. § 131.6. Criteria, as used in section 1313(c)(2)(A), refer to chemical-specific concentrations, toxicity levels, or narrative statements representing a quality of water that, if not exceeded, support a particular use of a waterbody. 40 C.F.R. § 131.3 ("Definitions").⁸

⁵ In addition to the above, Ecology must determine that the rule does not require actions that violate the requirements of other state or federal laws, RCW 34.05.328(1)(f), and that the rule does not impose more stringent requirements on private entities than on public entities unless required by federal law. RCW 34.05.328(1)(g). After adopting a rule regulating the same subject matter as another provision of federal law, Ecology is required to submit a report to the legislature identifying the existence of any overlap, duplication, or difference with federal law and making recommendations for any legislation necessary to eliminate or mitigate any adverse effects of such overlap, duplication or difference. RCW 34.05.328(4). The notice of proposed rulemaking required under RCW 34.05.320 must include a small business economic statement complying with RCW 19.85.040. RCW 34.05.320(1)(j).

⁶ Laws 1995 c 403 § 1.

⁷ CWA, Section 301(b)(1)(C); 303(e)(3)(A); National Toxics Rule (NTR), 57 Fed. Reg. 60848-01, 60851.

⁸ The term criteria is used in a different sense in section 304(a) of the CWA. "[I]n Section 304(a) the term criteria is used to describe the scientific information that EPA develops to be used as guidance by States, authorized Tribes and EPA when establishing water quality standards pursuant to 303(c)." EPA,

In 1987, Congress amended the CWA to require states to adopt criteria, both aquatic and human health-based, for those toxic pollutants that could interfere with designated uses of state waters.⁹ Citing the slow pace at which states were adopting criteria, EPA adopted the National Toxics Rule in 1992. The NTR established ambient water quality for states (including Washington) that had not yet established their own numeric ambient criteria for toxic pollutants.¹⁰

Ambient water quality criteria for human health protection is “designed to minimize the risk of adverse effects occurring to humans from chronic (lifetime) exposure to substances through the ingestion of drinking water and consumption of fish obtained from surface waters.”¹¹ EPA’s method for deriving health-based water quality criteria accordingly involves derivation of risk-based criteria, along with consideration of the rate at which adults consume fully contaminated fish over a lifetime (FCR).

EPA allowed states to choose risk levels “in the range of 10^{-6} to 10^{-4} to protect average exposed individuals and more highly exposed populations.”¹² Specifically, through the NTR process, EPA offered states the option of calculating ambient water quality based criteria based on either a 10^{-6} or 10^{-5} risk level for the general population. Washington opted to use the more restrictive 10^{-6} risk level.¹³ See WAC 173-201A-240(6) (“risk-based criteria for carcinogenic substances shall be selected such that the upper-bound excess cancer risk is less than or equal to one in one million.”); 40 C.F.R. § 131.36(b)(14)(iii).

EPA regards both risk levels as acceptable, so long as the selection provides at least a 10^{-4} risk level for the greatest consumers of fish.¹⁴ “EPA generally regulates pollutants treated as carcinogens in the range of 10^{-6} to 10^{-4} to protect average exposed individuals and more highly exposed populations.”¹⁵ “EPA also believes that criteria based on a 10^{-5} risk level are acceptable for the general population as long as States and

Methodology for Deriving Ambient Water Quality Criteria for the Protection of Human Health, EPA-822-B-00-004, at 1-4 (Oct. 2000).

⁹ CWA, Section 303(c)(2)(B).

¹⁰ NTR, 57 Fed. Reg. 60848-01, 60853 (Dec. 22, 1992).

¹¹ EPA, *Methodology for Deriving Ambient Water Quality Criteria for the Protection of Human Health*, EPA-822-B-00-004, at 1-11 (Oct. 2000).

¹² NTR, 57 Fed. Reg. 60855.

¹³ NTR, 57 Fed. Reg. 60848-01, 60868; 40 C.F.R. § 131.36(b)(14)(iii).

¹⁴ In general, the NTR established human health water quality criteria for states based on a 10^{-6} risk level. NTR, 57 Fed. Reg. 60860. A state could ask EPA to remove the state from the rule, and adopt human health criteria for a carcinogen at a 10^{-5} risk level. *Id.* at 60848-01, 60864. If a state convinced EPA a 10^{-5} risk level was appropriate, public notice and comment would not be required “because the Agency has considered in this rule that criteria based on either 10^{-5} or 10^{-6} risk levels meet the requirements of the Act.” *Id.*

¹⁵ NTR, 57 Fed. Reg. at 60855; *see also* 65 Fed. Reg. 31682, 31699 (May 18, 2000).

authorized Tribes ensure that the risk to more highly exposed subgroups (sportfishers or subsistence fishers) does not exceed the 10^{-4} level.”¹⁶

EPA and Washington have never assumed that the 10^{-6} risk policy set forth in WAC 173-201A-240(6) would apply to all consumers of fish. Otherwise, Washington would not have adopted its current risk policy, nor would EPA have approved coverage under the NTR where the criteria are based on a range of acceptable risk levels from 10^{-6} to 10^{-4} .¹⁷ EPA described this as a choice “to provide a high level of protection for the average population in order to provide what [Washington deemed] adequate protection for more sensitive populations.”¹⁸ In the context of the NTR, the 10^{-6} risk level is applicable to the general population on the assumption that NTR criteria are protective to 10^{-4} for higher consuming subpopulations.¹⁹

IV. The EPA Has Consistently Rejected that there is a Benefit from a more Stringent Water Quality Risk Policy.

As is summarized below, over the past twenty years EPA and the courts have repeatedly reaffirmed the NTR and Washington’s risk policy approach to the development of HHWQC. The EPA has consistently rejected as unjustified the idea of moving risk levels to 10^{-8} for the general population and 10^{-6} for more highly exposed subpopulations, on the grounds that such proposals afford no meaningful increase in human health protection. It has also considered and rejected the notion that the 10^{-6} to 10^{-4} risk policy offends notions of environmental justice.

¹⁶ EPA, *Methodology for Deriving Ambient Water Quality Criteria for the Protection of Human Health*, EPA-822-B-00-004, at 1-12. See also NTR, 57 Fed. Reg. 60848-01, 60863 (describing 10^{-5} level as “adequately protective”).

¹⁷ WAC 173-201A-240(6). EPA’s “policy in the NTR [is] to select the risk level that reflect[s] the policies or preferences of CWA programs in the affected States.” 65 Fed. Reg. 31682, 31699 (May 18, 2000).

¹⁸ EPA, Brief for the Defendant-Appellees, *Dioxin/Organochlorine Center v. Clarke*, Nos. 93-35973 & 93-36000 (May 31, 1994) at 48.

¹⁹ This approach to risk policy was well established by 1992 when EPA promulgated the NTR. The FDA was the first federal administrative agency to adopt 10^{-6} as a risk level. The FDA sought to establish amounts of carcinogenic compounds that when present as residue in human food would be consistent with “a zero tolerance (no residue)” policy. 33 Fed. Reg. 19226, 19226 (July 19, 1973). FDA originally proposed a one in one-hundred-million risk level. *Id.* at 19227. In its final rule, FDA determined a one-in-a-million risk was “essentially zero” or “de minimis.” 42 Fed. Reg. 10412 (Feb. 22, 1977).

The EPA itself engaged in quantitative risk assessment in deriving water quality criteria as early as 1980, concluding that given uncertainties, including variances of sensitivities and exposure levels, absolute criteria could not be established. 45 Fed. Reg. 79318, 79347 (Nov. 28, 1980). Instead, EPA presented a range of concentrations associated with risk levels of 10^{-5} , 10^{-6} , and 10^{-7} . *Id.* at 79348. EPA’s objective in deriving these water quality criteria was to estimate concentrations “which do not represent a significant risk to the public.” *Id.* at 79347.

See also Travis, C., Samantha A. Richter, Edmund A.C. Crouch, Richard Wilson, and Ernest D. Klema. “Cancer Risk Management: A Review of 132 Federal Regulatory Decisions.” *Environmental Science & Technology* 21.5 (1987): 419. Print. (“Prior to 1980, it was generally agreed that the de minimis risk was 10^{-6} per lifetime risk, regardless of population. . . for small-population risks, the de minimis risk is now considered to be a 10^{-4} lifetime risk.”).

It is the stated position of tribes and environmental groups that Ecology should be developing numeric human health criteria consistent with criteria recently adopted by the state of Oregon, and in the case of the Spokane River, with the very conservative criteria adopted by the Spokane Tribe. Oregon has adopted an extremely stringent fish consumption rate of 175 g/day, along with a stated 10^{-6} risk policy for the general population. The purported rationale for adopting such a stringent FCR is based on the fish consumption rates of the highest consuming subpopulation of tribes and recreational fishers. If, in fact, Ecology adopts a similar standard it will be rejecting the water quality criteria and risk policy approach consistently used and approved of by EPA as well as Ecology's current water quality risk policy for carcinogens.

A. *Dioxin/Organochlorine Center v. Clarke*, 57 F.3d 1517 (9th Cir. 1995).

The scope and intent of the 10^{-6} risk policy in WAC 173-201A-240(6) was a central issue in a 1994 challenge to a dioxin water quality improvement plan also known as a Total Maximum Daily Load allocation (TMDL) approved by EPA for the Columbia River. The dioxin TMDL was based on the same assumptions for the dioxin criterion set forth in the NTR, including a fish consumption rate of 6.5 g/day. The TMDL was challenged in federal court on the basis of evidence that the fish consumption rate for the high-consuming subpopulation of recreational fishers and tribes was closer to 150 g/day. The challengers contended that EPA should have applied WAC 173-201A-240(6) to derive a water quality criterion for dioxin that would protect all fish consumers at a level of 10^{-6} . In *Dioxin/Organochlorine Center v. Clarke*, 57 F.3d 1517, 1524 (9th Cir. 1995), the EPA successfully argued that acceptable risk levels are intended to be based on the general population, with a lenient range that extends to protect the most exposed populations at a lower, but still adequate degree.²⁰ The Ninth Circuit Court of Appeals agreed with the EPA that not all subpopulations, including those more exposed, must be protected to the same degree as the general population: "The one-in-one-million risk level mandated by the state water quality standards for the general population does not necessarily reflect state legislative intent to provide the highest level of protection for *all* subpopulations, but could reasonably be construed to allow for lower yet adequate protection of specific subpopulations." 57 F.3d at 1524 (emphasis in original).²¹

EPA had pointed out the conservative assumptions associated with the 6.5 g/day FCR and concurrent risk policy, including that the FCR and risk levels in the federal criteria are based on consumption of *maximally* contaminated fish, and are not intended

²⁰ EPA, Brief for the Defendant-Appellees, *Dioxin/Organochlorine Center v. Clarke*, Nos. 93-35973 & 93-36000 (May 31, 1994), at 48. EPA argued: "[T]he designated risk level is merely one factor included in the equation for calculating a numeric water quality standard. . . . The risk level chosen by a state is not part of the state's narrative criteria, nor is it a freestanding "standard" to be applied to the particularized exposure levels of specific individuals or sub-populations. . . . [S]tates may choose to provide a high level of protection for the average population in order to provide what they deem adequate protection for more sensitive populations." *Id.*

²¹ The risk policies in the NTR were also affirmed in *Natural Resources Defense Council v. EPA*, 16 F.3d 1395 (4th Cir. 1993) (rejecting argument that 6.5 grams per day FCR failed to protect subpopulations with higher than average fish consumption). EPA's range of acceptable risk levels was also upheld in other contexts. *E.g.*, *Ohio v. EPA*, 997 F.2d 1520, 1533 (D.C. Cir. 1993) (describing range of 10^{-6} to 10^{-4} as adequately protective of human health).

to reflect actual consumption rates. *Id.* According to the EPA, ambient water quality criteria consists of a range of concentrations associated with specified incremental lifetime risk levels. Thus, the FCR was “intended to represent only a subset of total fish consumption.” The FCR is the assumed amount of “maximum residue fish” consumed. EPA further asserted that consuming anadromous fish, like salmon, is unlikely to cause ingestion of contaminants at a rate equal to consuming maximum residue fish. EPA explained: “[T]he total fish consumption rate of various individuals is not determinative; the central question is whether the actual rate of ingestion [of a contaminant] is greater than that assumed by EPA.”²²

An important consideration in understanding the risk policy in the state of Washington is the timing and sequence of the state’s adoption of its risk policy and when the state became formally subject to the NTR. The risk policy, WAC 173-301A-249(5), was promulgated as a state regulation in October 1992.²³ The promulgation of the regulation referencing the NTR was included with revisions to the state Water Quality Standards, WAC 173-201A-240(6), five years later in November 1997.²⁴ In addition to the fact that the NTR does not extend the 10^{-6} risk level to all consumers, there is the intervening ruling in *Dioxin/Organochlorine Center* that the state policy does not reflect any intent to protect high consumers to the 10^{-6} risk level. A basic rule of statutory construction provides that the failure to amend an act following a judicial construction indicates approval of the construction.²⁵ Thus, if Ecology believed that the risk policy was intended to more broadly apply in Washington it would have amended the regulation prior to incorporating a reference to the NTR in the state Water Quality Standards. As adopted and in light of the federal court decision, the NTR as applied in Washington does not presume that all consumers are to be protected to a level of 10^{-6} .²⁶

B. 1995 EPA Final Water Quality Guidelines for the Great Lakes.

EPA confirmed its approach to the protection of high-consuming subpopulations in its 1995 Final Water Guidance for the Great Lakes, approving state adoption of a 10^{-5} risk level for the general population at a 15 g/day FCR because the most highly exposed populations of sport fishers and Native Americans would still be protected to a 10^{-4} level.²⁷ The EPA specifically addressed the consistency of the state water quality criteria with a federal Executive Order designed to ensure environmental justice for high-consuming subpopulations:

²² EPA, Brief for the Defendant-Appellees, *Dioxin/Organochlorine Center v. Clarke*, Nos. 93-35973 & 93-36000 (May 31, 1994) at 44. EPA’s water quality criteria guidance includes a margin of safety for water consumption. 65 Fed. Reg. 31682, 31693, col. 3 (May 18, 2000).

²³ WSR 92-24-037.

²⁴ WSR 97-23-064.

²⁵ *Hangman Ridge Training Stables, Inc. v. Safeco Title Ins. Co.*, 105 Wn.2d 778, 789, 719 P.2d 531 (1986).

²⁶ The sequence of all statutes relating to the same subject matter should be considered. *Dep’t of Labor and Industries v. Estate of MacMilan*, 117 Wn.2d 222, 229, 814 P.2d 194 (1991).

²⁷ EPA, Final Water Quality Guidelines for the Great Lakes System, 60 Fed. Reg. 15366-01 (March 23, 1995).

Commenters argued that a 15 gram per day assumption in the methodology would not adequately protect populations that consume greater than this amount (e.g., low-income minority anglers and Native Americans), and that such an approach therefore would be inconsistent with Executive Order 12898 regarding environmental justice (February 16, 1994, 59 FR 7629). EPA believes that the human health criteria methodology, including the fish consumption rate, will provide adequate health protection for the public, including more highly exposed sub-populations. In carrying out regulatory actions under a variety of statutory authorities, including the CWA, EPA has generally viewed an upper bound incremental cancer risk in the range of 10^{-4} to 10^{-6} as adequately protective of public health. As discussed above, the human health criteria methodology is based on a risk level of 10^{-5} . Therefore, if fish are contaminated at the level permitted by criteria derived under the final Guidance, individuals eating up to 10 times (i.e., 150 grams per day) the assumed fish consumption rate would still be protected at the 10^{-4} risk level. Available data indicate that, even among low-income minorities who as a group consume more fish than the population on average, the overwhelming majority (approximately 95 percent) consume less than 150 grams per day. . . . Understood in the larger context of the human health methodology and the final Guidance as a whole, therefore, EPA believes that the 15 gram per day fish consumption rate provides adequate health protection for the public, including highly exposed populations, and that the final Guidance is therefore consistent with Executive Order 12898.²⁸

C. 1999 EPA California Toxics Rule Response to Comments.

The principle of creating a more lenient range of acceptable risk as long as the populations with the highest threat are protected (typically to the 10^{-4} level) was further expressed by the EPA in response to objections to a one in one million (10^{-6}) risk level made by the Western Petroleum Association in the December, 1999 *California Toxics Rule Response to Comments Report*:

EPA uses a 10^{-6} risk level in establishing human health criteria guidance because it believes that a 10^{-6} risk level is an appropriate level of risk for the general population. This risk level is used by a majority of states and Tribes.

Subpopulations within a state may exist, such as subsistence anglers who as a result of greater exposure to a contaminant, are at greater risk than the assumed 70 kilogram person eating 6.5 grams per day of maximally contaminated fish and shellfish and drinking 2.0 liters per day of drinking water with pollutant levels meeting the water quality criteria. . . . By establishing rules at the 10^{-6} risk level, EPA applies a risk management policy which ensures protection for all exposed population groups (Draft Water Quality Criteria Methodology: Human Health, EPA 822-Z-98-001, August 1998, Appendix II, page 72). EPA acknowledges that at any given risk level for the general population, those segments of the population that are more highly exposed face a higher relative risk. For example, if fish are contaminated at a level permitted by criteria derived on the basis of a

²⁸ *Id.*

risk level of 10^{-6} , individuals consuming up to 10 times the assumed fish consumption rate would still be protected at a 10^{-5} risk level. Similarly individuals consuming 100 times the general population rate would be protected at a 10^{-4} risk level. EPA therefore believes that protection at the 10^{-6} risk level is a reasonable risk management decision protective of designated uses under the CWA.

....

The citation of programs that occasionally allow a risk level as high as 10^{-4} under specific circumstances does not prove to be inconsistent with protection of the general population at the 10^{-6} level recognizing that more highly exposed sub-populations such as ethnic or economically disadvantaged populations may face an excess risk level approaching 10^{-4} .

....

EPA disagrees that reliance on a 10^{-6} target risk level for setting water quality criteria is now mostly a historical artifact. The Food Quality Protection Act of 1996 (FQPA) amended the Federal Food, Drug, and Cosmetic Act to prohibit EPA from issuing tolerances for pesticide residues in or on food unless the agency determined that there is “reasonable certainty” that the residues will result in “no harm.” The legislative history of FQPA indicated Congressional support for EPA’s view that reasonable certainty of no harm would be met when a non-threshold risk is below a 10^{-6} level.

EPA specifically rejected several comments that the 10^{-6} to 10^{-4} risk policy offended notions of environmental justice:

EPA believes that this rule is consistent with the terms of the Executive Order (E.O.) on Environmental Justice. EPA rejects the notion that the rule is, in any respect, discriminatory against persons or populations because of their race, color, or national origin. The final rule establishes criteria that are designed to ensure protection of the public, including highly exposed populations. While some groups and individuals, including some low income and minority persons and populations, may face a greater risk of adverse health effects than the general population due to their particular fish consumption patterns, EPA believes that these groups will nonetheless receive a level of public health protection within the range that EPA has long considered to be appropriate in its environmental programs (e.g., 10^{-4} to 10^{-6} incremental cancer risk). Obviously, as long as there is variability in fish consumption patterns among various segments of the population, it would be impossible for EPA to ensure that all groups would face identical risk from consuming fish. Therefore, EPA has sought to ensure that, after attainment of water quality criteria in ambient waters, no group is subject to increase cancer risks greater than the risk range that the EPA has long considered protective. EPA disagrees that individuals who consume up to a pound of fish per day would face a 10^{-3} cancer risk. Given that the basis of the criteria are a 6.5 gm/day assumption at a 10^{-6} risk level, individuals who consume a pound of fish

per day would be protected within the established acceptable range of 10^{-4} to 10^{-6} , consistent throughout current EPA program office guidance and regulatory actions.²⁹

D. 2000 EPA Methodology for Deriving Ambient Water Quality Criteria for the Protection of Human Health.

In 2000, EPA affirmed its national policy on the acceptable risk level for human health criteria in the final edition of its *Methodology for Deriving Ambient Water Quality Criteria for the Protection of Human Health*. In that guidance document EPA described the choice of a default consumption rate and acceptable cancer risk as a risk management decision that integrates the risk assessment with engineering data, social, economic and political concerns.³⁰ EPA, again, confirmed a one in one million standard for the general population with a range extending to one in ten thousand, as long as the most highly exposed populations are protected:

For deriving 304(a) criteria or promulgating water quality criteria for States and Tribes under Section 303(c) based on the 2000 Human Health Methodology, EPA intends to use the 10^{-6} risk level, which the Agency believes reflects an appropriate risk for the general population. EPA's program office guidance and regulatory actions have evolved in recent years to target a 10^{-6} risk level as an appropriate risk for the general population. EPA has recently reviewed the policies and regulatory language of other Agency mandates (e.g., the Clean Air Act Amendments of 1990, the Food Quality Protection Act) and believes the target of a 10^{-6} risk level is consistent with Agency-wide practice.

EPA believes that both 10^{-6} and 10^{-5} may be acceptable for the general population and that highly exposed populations should not exceed a 10^{-4} risk level. States or Tribes that have adopted standards based on criteria at the 10^{-5} risk level can continue to do so, if the highly exposed groups would at least be protected at the 10^{-4} risk level. However, EPA is not automatically assuming that 10^{-5} will protect "the highest consumers" at the 10^{-4} risk level. Nor is EPA advocating that States and Tribes automatically set criteria based on assumptions for highly exposed population groups at the 10^{-4} risk level. The Agency is simply endeavoring to add that a specific determination should be made to ensure that highly exposed groups do not exceed a 10^{-4} risk level. EPA understands that fish consumption rates vary considerably, especially among subsistence populations, and it is such great variation among these population groups that may make either 10^{-6} or 10^{-5} protective of those groups at a 10^{-4} risk level. Therefore, depending on the

²⁹ EPA, *California Toxics Rule Response to Comments Report*, CTR-002-005a (Dec. 1999). http://water.epa.gov/lawsregs/rulesregs/ctr/upload/2009_03_26_standards_rules_ctr_responses.pdf (emphasis supplied).

³⁰ EPA defined risk management as "Risk management is the process of selecting the most appropriate guidance or regulatory actions by integrating the results of risk assessment with engineering data and with social, economic, and political concerns to reach a decision." EPA, *Methodology for Deriving Ambient Water Quality Criteria for the Protection of Human Health*, EPA-822-B-00-004, at 2-4 (Oct. 2000).

consumption patterns in a given State or Tribal jurisdiction, a 10^{-6} or 10^{-5} risk level could be appropriate. In cases where fish consumption among highly exposed population groups is of a magnitude that a 10^{-4} risk level would be exceeded, a more protective risk level should be chosen. . . .

Adoption of a 10^{-6} or 10^{-5} risk level, both of which States and authorized Tribes have chosen in adopting water quality standards to date, represents a generally acceptable risk management decision, and EPA intends to continue providing this flexibility to States and Tribes. EPA believes that such State or Tribal decisions are consistent with Section 303(c) if the State or authorized Tribe has identified the most highly exposed subpopulation, has demonstrated that the chosen risk level is adequately protective of the most highly exposed subpopulation, and has completed all necessary public participation. . . .

It is important to understand that criteria for carcinogens are based on chosen risk levels that inherently reflect, in part, the exposure parameters used to derive those values. Therefore, changing the exposure parameters also changes the risk. Specifically, the incremental cancer risk levels are *relative*, meaning that any given criterion associated with a particular cancer risk level is also associated with specific exposure parameter assumptions (e.g., intake rates, body weights). When these exposure parameter values change, so does the relative risk. For a criterion derived on the basis of a cancer risk level of 10^{-6} , individuals consuming up to 10 times the assumed fish intake rate would not exceed a 10^{-5} risk level. Similarly, individuals consuming up to 100 times the assumed rate would not exceed a 10^{-4} risk level. Thus, for a criterion based on EPA's default fish intake rate (17.5 gm/day) and a risk level of 10^{-6} , those consuming a pound per day (i.e., 454 grams/day) would potentially experience between a 10^{-5} and a 10^{-4} risk level (closer to a 10^{-5} risk level). (Note: Fish consumers of up to 1,750 gm/day would not exceed the 10^{-4} risk level.) If a criterion were based on high-end intake rates and the relative risk of (10^{-6}), then an average fish consumer would be protected at a cancer risk level of approximately 10^{-8} . The point is that the risks for different population groups are not the same.³¹

EPA has not revised the national policy on the acceptable range of risk levels reflected in the 1992 NTR, the 1995 *Dioxin/ Organochlorine Center* decision, the 1995 Final Water Quality Guidance for the Great Lakes, the 1999 California Toxics Rule response to comments, or the 2000 guidance document for deriving human health criteria. This risk assessment policy remains in force today.

E. Federal FDA and EPA Programs Have Consistently Seen No Benefit from Risk Policies Below 10^{-6} .

In approving the CFR, the EPA rejected comments that criteria based on general population consumption rates at 10^{-6} was not protective of higher consuming tribal population. The agency specifically found that there was no justification to go to a more stringent risk policy level to protect tribal consumers:

³¹ *Id.* at 2-6 (emphasis supplied).

EPA disagrees that reliance on a 10^{-6} target risk level for setting water quality criteria is now mostly a historical artifact. The Food Quality Protection Act of 1996 (FQPA) amended the Federal Food, Drug, and Cosmetic Act to prohibit EPA from issuing tolerances for pesticide residues in or on food unless the agency determined that there is “reasonable certainty” that the residues will result in “no harm.” The legislative history of FQPA indicated Congressional support for EPA’s view that reasonable certainty of no harm would be met when a non-threshold risk is below a 10^{-6} level.³²

The position taken by EPA in this comment is consistent with the assessment of acceptable risk policy for carcinogens across EPA programs and regulations under the Food and Drug Administration (FDA). FDA concluded, for example, that a one in a million risk level “imposes no additional risk of cancers to the public.”³³ FDA stated that this risk level is the same as finding that the risk is of no public health consequence or that it is insignificant.

The EPA and FDA through the 1970’s and 1980’s considered risk policies at 10^{-7} and 10^{-8} . Those policies were not accepted on the grounds that they offered no meaningful additional protection to public health. FDA in particular moved from a risk policy of 10^{-8} to 10^{-6} as a more reasonable basis for regulations and one that represents “an operational definition of no-residue.”³⁴

V. Conclusion

In deriving state HHWQC Ecology will have to assess the cost benefit of its proposed regulation. If the state adopts criteria on the same basis as the state of Oregon, the resulting standards will reflect a significant change in the current water quality risk policy. While Ecology may do that under federal and state law, it must demonstrate and document some benefit to public health by doing so. This will be a significant challenge to Ecology when the current policy to protect the general public at a risk level of one in one million has been deemed across EPA and FDA programs for decades to be the functional equivalent of zero exposure at all exposure levels in the community.

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³² See fn. 29.

³³ Cosmetics; Proposed Ban on the Use of Methylene Chloride as an Ingredient of Aerosol Cosmetic Products, 50 Fed. Reg. 51551-51559 (Dec. 18, 1985).

³⁴ Criteria and Procedures for Evaluating Assays for Carcinogenic Residues in Edible Products of Animals, 42 Fed. Reg. 10412 (Feb. 22, 1977).